



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/677,861

10/03/2003

Bruno Criere

1017751-000039

4606

21839 7590 07/02/2010
BUCHANAN, INGERSOLL & ROONEY PC
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

07/02/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com
offserv@bipc.com

Office Action Summary	Application No. 10/677,861	Applicant(s) CRIERE ET AL.	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72 and 76-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72 and 76-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) ☐ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

DETAILED ACTION

Response to Arguments

1. The response filed on **3/15/2010** has been entered.
2. Applicant's arguments filed 3/15/2010 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 72 and 76-78 are pending in this office action.

Priority

5. The petition filed under 37 CFR 1.78(a)(3) was DISMISSED. The petition under 37 CFR 1.55(c) was DISMISSED (see Decision on Petition by the office on 6/16/10). Therefore the rejections of record are maintained.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 72 stands rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/03693 or (English version US Patent 7,101,574) for the reasons made of record in Paper No. 20100120 and as follows.

Criere et al. teach a pharmaceutical composition comprising fenofibrate that is used in the treatment of hyperlipidemias, hypercholesterolemias and hypertriglyceridemias (see col. 1, lines 9-14), wherein the composition is in the form of granules having a neutral core (i.e., neutral microgranules) and an active layer wherein the active layer comprises fenofibrate, surfactant, and the binding cellulose HPMC (see col. 4, lines 23-25) and the binding cellulose is between 5/1 and 15/1 and the binding cellulose is between 5 and 12% of the combined weight of the neutral core, fenofibrate and the binding cellulose (see col. 2, lines 45-52).

With regards to the limitation "reducing food effect when treating hypertriglyceridemias", Criere teaches the administration of fenofibrate to adults with endogenous hyperlipidemia etc., and therefore administration of the drug to the disease afflicted population inherently would reduce the food effect, wherein Crier's population of patients include patients suffering from hyperlipidemias (see col. 1, lines 9-14).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1618

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 72 and 76-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Criere et al. (WO 01/03693 or English version US Patent 7,101,574) in view of U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER; 1997) and as evidence by Munoz et al (IDS Ref. # 3 of 9/14/06) for the reasons made of record in Paper No. 20100120 and as follows.

Criere is applied here as discussed above in Para 7. However Criere et al. fail to teach treating a patient fed a high fat containing meal and that the bioavailability of fenofibrate administered to their patients is equivalent to when their patients have fasted and also fails to teach that the patient is fed at least 800-1000 calories, of which 50% are from fat.

U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) October 1997 teaches with regards to instant claims 76-78, that food effect bioavailability. The CDER specifically teach that the patient is fed a high fat containing meal (i.e., breakfast) and the bioavailability is determined based on when the patient has fasted (i.e., before breakfast; as required by instant claim 76, see pages 5-6). Also CDER teaches that the patients should be fed a high caloric meal of at least 1000 calories which further comprises 50% fat (as required by instant claim 77, see page 5 under test sec. D). As evidence by Munoz et al. the digestive absorption of Lipanthyl® 200 Micronized is less influenced by the lipid content of food than standard fenofibrate. The comparison of digestive absorption obtained after administration of Lipanthyl® 200 Micronized and 300 mg of standard fenofibrate during a low fat meal, versus during a high fat meal, shows that the variation of this absorption is reduced by a factor of three in the high fat meal (Fig. 5).

One of ordinary skill in the art would have expanded the teaching of Criere by administering a micronized fenofibrate to patients with hyperlipidemia as taught by Criere, by incorporating the teachings by the CDER for achieving bioavailability of fenofibrate in high fat meals.

It would have been obvious to have administered a micronized fenofibrate to treat hypertriglyceride and reduce the food effect simultaneously because it is known that the micronized drug form of fenofibrate results in high bioavailability together with polymers; surfactants and other excipients. Specifically Criere teaches that micronized fenofibrate increases/enhances its bioavailability (see abstract).

Art Unit: 1618

As to the limitation "wherein said patient fed a therapeutic life style change diet", this limitation is obvious and intrinsically met, because eating a healthy life style change diet is well known in the art, and is recommended with fenofibrate administration.

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
6/21/10

/Robert C. Hayes/
Primary Examiner, Art Unit 1649